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#### **INFORMATION NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee/Council

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Subject: Proposal for a Regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC  
- Outcome of the European Parliament's first reading,  
(Strasbourg, 22 to 25 October 2018)

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#### **I. INTRODUCTION**

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure <sup>1</sup>, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

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<sup>1</sup> OJ C 145, 30.6.2007, p.5

In this context, the chair to the Committee on Agriculture and Rural Development Czesław Adam SIEKIERSKI (EPP, PL) presented a compromise amendment (amendment 94) to the proposal for a Regulation on behalf of the Committee on Agriculture and Rural Development. This amendment had been agreed during the informal contacts referred to above. No other amendments were tabled.

## II. VOTE

When it voted on 25 October 2018, the plenary adopted the compromise amendment (amendment 94) to the proposal for a Regulation. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto<sup>2</sup>.

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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<sup>2</sup> The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol "■" indicates deleted text.

## **Manufacture, placing on the market and use of medicated feed \*\*\*I**

**European Parliament legislative resolution of 25 October 2018 on the proposal for a regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (COM(2014)0556 – C8-0143/2014 – 2014/0255(COD))**

### **(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2014)0556),
  - having regard to Article 294(2) and Article 43 and Article 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0143/2014),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 21 January 2015<sup>3</sup>,
  - After consulting the Committee of the Regions,
  - having regard to the provisional agreement approved by the committee responsible under Rule 69f(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 8 May 2018 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rules 59 and 39 of its Rules of Procedure,
  - having regard to the report of the Committee on Agriculture and Rural Development and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0075/2016),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

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<sup>3</sup> OJ C 242, 23.7.2015, p. 54.

- Instructs its President to forward its position to the Council, the Commission and the national parliaments.

**Position of the European Parliament adopted at first reading on 25 October 2018 with a view to the adoption of Regulation (EU) 2018/... of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) and point (b) of *Article* 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>4</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure<sup>5</sup>,

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<sup>4</sup> OJ C 242, 23.7.2015, p. 54.

<sup>5</sup> Position of the European Parliament of 25 October 2018.

Whereas:

- (1) Council Directive 90/167/EEC<sup>6</sup> constitutes the Union's regulatory framework for the preparation, placing on the market and use of medicated feed.
- (2) Livestock production occupies a very important place in the agriculture of the Union. The rules concerning medicated feed have a significant influence on the keeping and on the rearing of animals, including non-food-producing animals, and on the production of products of animal origin.
- (3) The pursuit of a high level of protection of human health is one of the fundamental objectives of Union food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>7</sup>, and the general principles laid down in that Regulation should apply to the placing on the market and use of feed without prejudice to more specific Union legislation. In addition, the protection of animal health constitutes one of the general objectives of Union food law.
- (4) ***Prevention of disease is better than cure. Medicinal treatments, especially with antimicrobials, should never replace good husbandry, bio-security and management practices.***

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<sup>6</sup> Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42).

<sup>7</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (5) Experience with the application of Directive 90/167/EEC has shown that further measures should be taken to strengthen the effective functioning of the internal market and to explicitly give and improve the possibility to treat non-food-producing animals with medicated feed.
- (6) Medicated feed is one of the routes for the *oral* administration of veterinary medicinal products **■**. *Medicated feed is a homogeneous mixture of feed and veterinary medicinal products. Other routes for oral administration, such as mixing of water for drinking with a veterinary medicinal product or manual mixing of a veterinary medicinal product into feed should not fall within the scope of this Regulation.* The authorisation for use in feed, the manufacture, distribution, advertising and supervision of those veterinary medicinal products are governed by *Regulation (EU) 2018/...* of the European Parliament and of the Council<sup>8+</sup>.
- (7) *Regulation (EU) 2018/...<sup>++</sup> applies to veterinary medicinal products, including those products which Directive 90/167/EEC referred to as 'pre-mixes', until such time as those products are included in medicated feed or intermediate products, after which this Regulation applies to the exclusion of Regulation (EU) 2018/...<sup>++</sup>.*

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<sup>8</sup> *Regulation (EU) 2018/... of the European Parliament and of the Council of ... on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L ...).*

<sup>+</sup> *OJ: please insert the number, date and OJ reference of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

<sup>++</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

- (8) As a type of feed, medicated feed ***and intermediate products*** fall within the scope of Regulations (EC) No 183/2005<sup>9</sup>, (EC) No 767/2009<sup>10</sup>, (EC) No 1831/2003<sup>11</sup> and Directive 2002/32/EC of the European Parliament and of the Council<sup>12</sup>. ***Thus, whenever medicated feed is manufactured with a compound feed all relevant Union legislation on compound feed applies and whenever medicated feed is manufactured from a feed material, all relevant Union legislation on feed material applies. This applies to feed business operators, whether they operate in a feed mill, with a specially equipped vehicle or on-farm, as well as to feed business operators storing, transporting or placing on the market medicated feed and intermediate products.***

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<sup>9</sup> Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

<sup>10</sup> Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

<sup>11</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

<sup>12</sup> Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

- (9) Specific provisions for medicated feed and intermediate products should be established concerning facilities and equipment, personnel, manufacture, quality control, storage, transport, record-keeping, complaints, product recalls and labelling.
- (10) Medicated feed imported into the Union must satisfy the general obligations laid down in Article 11 of Regulation (EC) No 178/2002 and the import conditions laid down in Regulation (EC) No 183/2005 and in Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>13</sup>. Within that framework, medicated feed imported into the Union should be considered as falling within the scope of this Regulation.
- (11) Without prejudice to the general obligations laid down in Article 12 of Regulation (EC) No 178/2002 concerning exports of feed to third countries, this Regulation should apply to medicated feed and intermediate products which are manufactured, stored, transported or placed on the market within the Union with the intention to be exported. However, the specific requirements concerning labelling, prescription and use of medicated feed and intermediate products, laid down in this Regulation, should not apply to products intended to be exported.

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<sup>13</sup> ***Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).***

- (12) *While veterinary medicinal products and the supply thereof are covered by Regulation (EU) 2018/...<sup>+</sup>, intermediate products are not and should therefore be specifically covered by this Regulation in a corresponding way.*
- (13) Medicated feed should be manufactured only with veterinary medicinal products *authorised for the purpose of the manufacture of medicated feed* and the compatibility of all compounds used should be ensured for the purpose of safety and efficacy of the product. Additional specific requirements or instructions for the inclusion of the veterinary medicinal products into feed should be provided for to ensure safe and efficient treatment of the animals.
- (14) Homogeneous *dispersion* of the veterinary medicinal product into the feed is also crucial for the manufacture of a safe and efficient medicated feed. Therefore, the possibility to establish criteria, such as target values, for the homogeneity of the medicated feed should be provided for.

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

- (15) Feed business operators may manufacture within one establishment a broad range of feeds for different target animals and containing different types of compounds such as feed additives or veterinary medicinal products. The manufacture of different types of feed after each other in the same production line may result in the presence of traces of *an active* substance in the line, which ends up in the beginning of the production of another feed. That transfer of traces of *an active* substance from one production *batch* to another is called ‘*cross-contamination*’.
- (16) *Cross-contamination* may occur during manufacture, processing, storage or transport of feed where the same production and processing equipment, *including for mobile mixing*, storage facilities or means of transport are used for feed with different components. For the purposes of this Regulation, the concept of *cross-contamination* is used specifically to designate the transfer of traces of an active substance contained in a medicated feed to a non-target feed ■ . *Contamination of non-target feed with* active substances contained in medicated feed ■ should be avoided or kept as low as possible.

- (17) In order to protect animal health, human health and the environment, maximum levels of ***cross-contamination for active substances in non-target feed*** should be established, based on a scientific risk assessment performed by the European Food Safety Authority (EFSA) and ***in cooperation with the European Medicines Agency, as well as*** taking into account the application of good manufacturing practice and the “as low as reasonably achievable” (“ALARA”) principle. ***Until the completion of that scientific risk assessment, national maximum levels of cross-contamination for active substances in non-target feed, regardless of its origin, should apply,*** taking into account the unavoidable ***cross-contamination*** and the risk caused by the active substances concerned.
- (18) Labelling of medicated feed should comply with the general principles laid down in Regulation (EC) No 767/2009 and should be subject to specific labelling requirements in order to provide the user with the information necessary to correctly administer the medicated feed. Similarly, limits for the deviations of the labelled content of medicated feed from the actual content should be established.

- (19) Medicated feed *and intermediate products* should be marketed in sealed *packages or* containers for safety reasons and to protect users' interests. *This should not apply to mobile mixers that supply medicated feed directly to the animal keeper.*
- (20) *The advertising of medicated feed could affect public and animal health and distort competition. Therefore, advertising of medicated feed should satisfy certain criteria. Veterinarians can properly evaluate the information available in advertising because of their knowledge and experience in animal health. The advertising of medicated feed to persons who cannot properly appreciate the risk associated with their use may lead to medicine misuse or overconsumption which is liable to harm public or animal health, or the environment.*
- (21) For intra-Union trade *and import* of medicated feed, it should be ensured that the veterinary medicinal products contained therein *are allowed for use* in the destination Member State in accordance with *Regulation (EU) 2018/...<sup>+</sup>*.

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

(22) *It is important to take into consideration the international dimension of the development of antimicrobial resistance. Antimicrobial resistant organisms can spread to humans and animals in the Union and third countries through consumption of products of animal origin, from direct contact with animals or humans or by other means. This has been recognised in Article 118 of Regulation 2018/...<sup>+</sup> which provides that operators in third countries are to respect certain conditions relating to antimicrobial resistance for animals and products of animal origin exported from such third countries to the Union. This is to be taken into consideration also in respect of the use of antimicrobial medicinal products concerned if they are administered via medicated feed. Furthermore, in the context of international cooperation and in line with the activities and policies of international organisations such as the World Health Organization (WHO) Global Action Plan and the Strategy on Antimicrobial Resistance and the Prudent use of Antimicrobials of the World Organisation for Animal Health, steps restricting the use of medicated feed containing antimicrobials in order to prevent a disease should be considered worldwide for animals and products of animal origin exported from third countries to the Union.*

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

- (23) Feed business operators manufacturing – whether they operate in a feed mill, with a specially equipped *vehicle* or on-farm – storing, transporting or placing on the market medicated feed and intermediate products, should be approved by the competent authority, in accordance with the approval system laid down in Regulation (EC) No 183/2005, in order to ensure both feed safety and product traceability. ***Feed business operators dealing with some lower risk activities, such as certain types of transport, storage and retail, should be exempted from the approval obligation, however this should not exempt them from the registration obligation under the registration system laid down in Regulation (EC) No 183/2005. To ensure appropriate use and full traceability for medicated feed, retailers of medicated feed for pets and keepers of fur animals feeding animals with medicated feed, which are not subject to the approval obligations, should provide information to competent authorities.*** Provision should be made for a transition procedure concerning establishments already approved under Directive 90/167/EEC.
- (24) ***Care should be taken to ensure that the medicated-feed-handling requirements laid down in this Regulation and in the delegated and implementing acts adopted pursuant to this Regulation concerning feed business operators, in particular on-farm mixers, are feasible and practical.***

- (25) In order to ensure the safe use of medicated feed, its supply and use should be subject to presentation of a valid veterinary prescription *for medicated feed* which has been issued *by a veterinarian* after examination *or any other proper assessment of the health status* of the animals to be treated. However, the possibility to manufacture medicated feed before a *veterinary* prescription *for medicated feed* is presented to the manufacturer should not be excluded. *Where medicated feed has been prescribed in a Member State by a veterinarian, it should as a general rule be possible for that veterinary prescription for medicated feed to be recognised and for the medicated feed to be dispensed in another Member State. By way of derogation, a Member State could allow a prescription for medicated feed to be issued by a professional person qualified to do so, other than a veterinarian, in accordance with applicable national law at the time of entry into force of this Regulation. Such a prescription for medicated feed issued by such a professional person, other than a veterinarian, should be valid only in that Member State and should exclude the prescription of medicated feed containing antimicrobial veterinary medicinal products and of any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.*

- (26) In order to ensure prudent use – *which means appropriate use of medicines in accordance with the veterinary prescription for medicated feed and the summary of product characteristics* – of medicated feed for food-producing animals *and fur animals* and therefore provide the basis for the assurance of a high level of protection of *animal health and* public health, specific conditions concerning the use and the validity of the *veterinary prescription for medicated feed*, compliance with the withdrawal period and record-keeping by the animal *keeper, where appropriate*, should be provided for.
- (27) Taking into account the serious public health risk posed by antimicrobial resistance, it is appropriate to limit the use of medicated feed containing antimicrobials for █ animals. *Prophylaxis* or use of medicated feed to enhance the performance of █ animals should █ not be allowed, *except, in certain cases, as regards medicated feed containing antiparasitics and immunological veterinary medicinal products. The use of medicated feed containing antimicrobials for metaphylaxis should only be allowed when the risk of spread of an infection or of an infectious disease is high, in accordance with Regulation 2018/...<sup>+</sup>.*

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

- (28) *The use of medicated feed containing some antiparasitics should be based on the knowledge of the parasite infestation status in the animal or group of animals. Despite the measures that farmers take to ensure good hygiene and biosecurity, animals may suffer from diseases which need to be prevented by medicated feed for reasons of both animal health and welfare. Animal diseases which are transmissible to humans may also have a significant impact on public health. Therefore the use of medicated feed containing immunological veterinary medicinal products or some antiparasitics should be allowed in the absence of a diagnosed disease.*
- (29) *In accordance with Regulation (EC) No 1831/2003, the ban on the use of antibiotics as growth promoting agents as from 1 January 2006 should be strictly adhered to and properly enforced.*
- (30) *The 'One Health' concept, endorsed by the WHO and the World Organization for Animal Health (OIE), recognises that human health, animal health and ecosystems are interconnected and it is therefore essential for both animal and human health to ensure prudent use of antimicrobial medicinal products in food-producing animals.*
- (31) *On 17 June 2016, the Council adopted conclusions on the next steps under a One Health approach to combat antimicrobial resistance. On 13 September 2018, the European Parliament adopted a resolution on a European One Health Action Plan against Antimicrobial Resistance.*

- (32) A system for the collection *or discard* of unused or expired *intermediate* products *and medicated feed* should be **■** in place, *including through existing systems and when managed by feed business operators*, in order to control any risk that such products might raise with regard to the protection of animal or human health or the environment. *The decision as to who is responsible for such collection or discard system should remain a national competence. Member States should take measures to ensure that appropriate consultations with relevant stakeholders are carried out to ensure the fitness for purpose of such systems.*
- (33) In order to comply with the objectives of this Regulation and to take into account technical progress and scientific developments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the establishment of specific *maximum levels of cross-contamination for active substances in non-target feed and methods of analysis for active substances in feed* and of the amendment to the Annexes to this Regulation. Those Annexes concern provisions on feed business operators obligations related to the manufacture, storage, transport and placing on the market of medicated feed and intermediate products, the *list of antimicrobial active substances which are most commonly used in medicated feed*, the labelling requirements for medicated feed and intermediate products, the permitted tolerances for the compositional labelling of medicated feed or intermediate products and the *mandatory information* to be *included in* the veterinary prescription for medicated feed. *It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>14</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.*

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<sup>14</sup> OJ L 123, 12.5.2016, p. 1.

- (34) In order to ensure uniform conditions for the implementation of this Regulation regarding the establishment of homogeneity criteria for medicated feed, *as well as a model format for the veterinary prescription for medicated feed*, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>15</sup>.
- (35) Member States should lay down rules on penalties applicable to infringement of this Regulation and should take all measures necessary to ensure that they are implemented. Such penalties should be effective, proportionate and dissuasive.

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<sup>15</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (36) *In order to ensure that all manufacturers of medicated feed, including on farm mixers, apply Annex II to Regulation (EC) No 183/2005, that Regulation should be amended accordingly.*
- (37) Since the objectives of this Regulation, namely ensuring a high level of protection of human and animal health, providing adequate information for users and strengthening the effective functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

## Chapter I

*Subject matter, scope and definitions*

### *Article 1*

*Subject matter*

***This Regulation lays down specific provisions regarding medicated feed and intermediate products, which are additional to Union legislation on feed and apply without prejudice in particular to Regulations (EC) No 1831/2003, (EC) No 183/2005 and (EC) No 767/2009 and Directive 2002/32/EC.***

### Article 2

Scope

1. This Regulation applies to:

- (a) the manufacture, storage and transport of medicated feed and intermediate products;
- (b) the placing on the market, including import ***from third countries***, and use of medicated feed and intermediate products;
- (c) the export to third countries of medicated feed and intermediate products. However, Articles 9, ***16, 17 and 18*** shall not apply to medicated feed and intermediate products whose label indicates that they are intended for export to third countries.

2. ***This Regulation does not apply to veterinary medicinal products as defined in Regulation (EU) 2018/...<sup>+</sup> except where such products are included in a medicated feed or an intermediate product.***

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

Article 3  
Definitions

1. For the purposes of this Regulation, the following definitions apply:
- (a) the definitions of 'feed', 'feed business' and 'placing on the market' as laid down, respectively, in points 4, 5 and 8 of Article 3 of Regulation (EC) No 178/2002;
  - (b) the definitions of 'feed additives' and 'daily ration' as laid down, respectively, in points (a) and (f) of Article 2(2) of Regulation (EC) No 1831/2003;
  - (c) the definitions of 'food-producing animal', '***non-food-producing animals***', '***fur animals***', 'feed materials', 'compound feed', 'complete feed', 'complementary feed', 'mineral feed', 'minimum storage life', 'batch', 'labelling' and 'label' as laid down, respectively, in points (c), (d), (e), (g), (h), (i), (j), (k), (q), (r), (s) and (t) of Article 3(2) of Regulation (EC) No 767/2009;
  - (d) the definition of 'establishment' as laid down in point (d) of Article 3 of Regulation (EC) No 183/2005;
  - (e) the definitions of 'official controls' and 'competent authorities' as laid down, respectively, in Article 2(1) ***and in point 3 of Article 3***, of Regulation (EU) 2017/625;
  - (f) the definitions of 'veterinary medicinal product', '***active substance***', '***immunological veterinary medicinal product***', '***antimicrobial***', '***antiparasitic***', '***antibiotic***', '***metaphylaxis***', '***prophylaxis***', ***and*** "withdrawal period", as laid down, respectively, in points 1, 3, 5, 12, 13, 14,, 15, 16 and 34 of Article 4 of ***Regulation (EU) 2018/...<sup>+</sup>***, ***and 'summary of the product characteristics' referred to in Article 35 of that Regulation.***

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

2. The following definitions also apply:

(a) 'medicated feed' means *a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous* mixture of one or more veterinary medicinal products or intermediate products with *feed materials or compound feed*;

(b) 'intermediate product' means *a feed, which is not ready to be directly fed to animals without further processing, consisting of a homogenous* mixture of one or more veterinary medicinal products with *feed materials or compound feed, exclusively* intended to be used for the manufacture of medicated feed;

■

(c) 'non-target feed' means feed, *whether medicated or not*, which is not intended to contain a specific *active substance*;

■

(d) '*cross-contamination*' means *contamination of a non-target feed with an active substance originating from the previous use of the facilities or equipment*;

(e) 'feed business operator' means any natural or legal person responsible for ensuring that the requirements of this Regulation are met within the feed business under that person's control;

■

(f) 'mobile mixer' means a feed business operator with a feed establishment consisting of a specifically equipped *vehicle* for the manufacture of medicated feed;

(g) 'on-farm mixer' means a feed business operator manufacturing medicated feed *for the exclusive use* on *its* farm ■ ;

- (h) *'veterinary prescription for medicated feed' means a document issued by a veterinarian for a medicated feed;*
- (i) *'advertising' means the making of a representation in any form in connection with medicated feed and intermediate products in order to promote prescription or use of medicated feed comprising also the supply of samples and sponsorships;*
- (j) *'animal keeper' means any natural or legal person responsible for animals, whether on a permanent or on a temporary basis.*

## Chapter II

### Manufacture, storage, transport and placing on the market

#### Article 4

##### General obligations

1. Feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products in compliance with Annex I.
2. ***This Article shall not apply to farmers that only buy, store ■ or transport medicated feed ■ for the exclusive use on their farm.***

*Notwithstanding the first subparagraph, Section 5 of Annex I shall apply to such farmers.*

3. ***Article 101(2) and Article 105(9) of Regulation (EU) 2018/...<sup>+</sup> shall apply, mutatis mutandis, to the supply of intermediate products.***
4. ***Article 57 and Section 5 of Chapter IV of Regulation (EU) 2018/...<sup>+</sup> shall apply, mutatis mutandis, to medicated feed and intermediate products.***

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

Article 5  
Composition

1. Medicated feed and intermediate products shall only be manufactured from veterinary medicinal products, ***including veterinary medicinal products intended to be used in accordance with Article 112, Article 113 or Article 114 of Regulation (EU) 2018/...<sup>+</sup>***, authorised for the purpose of the manufacture of medicated feed in accordance with the conditions laid down in ***that Regulation***.
  
2. The ***feed business operator manufacturing*** the medicated feed ***or intermediate product*** shall ensure ***that***:

- (a) the medicated feed ***or intermediate product*** is manufactured in compliance with the relevant conditions laid down in ***the veterinary prescription for medicated feed or, in the cases referred to in Article 8 of this Regulation, in the summary of the product characteristics, related to the veterinary medicinal products to be incorporated in the feed; those conditions shall include particular provisions regarding known interactions between the veterinary medicinal products and the feed that may impair the safety or the efficacy of the medicated feed or intermediate product;***

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD))***.

- (b) a feed additive ***authorised as a coccidiostat or a histomonostat*** for which a maximum content is set in the respective authorisation act is not incorporated in the medicated feed ***or intermediate product*** if it is already used as active substance in the veterinary medicinal product;
- (c) ***where the active substance in the veterinary medicinal product is the same as a substance in a feed additive contained in the feed concerned, the total content of that active substance in the medicated feed does not exceed the maximum content set out in the veterinary prescription for the medicated feed or, in the cases referred to in Article 8, in the summary of product characteristics;***
- (d) ***the veterinary medicinal products incorporated in the feed combine with it to form a stable mixture for the entire storage life of the medicated feed, and respect the expiry date of the veterinary medicinal product, as referred to in point (f) of Article 10(1) of Regulation (EU) 2018/...<sup>+</sup>, provided that the medicated feed or intermediate product is properly stored and handled.***
3. ***Feed business operators supplying medicated feed to the animal keeper shall ensure that the medicated feed complies with the prescription referred to in Article 16.***

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

Article 6  
Homogeneity

1. Feed business operators manufacturing medicated feed *or intermediate products* shall ensure **that** the veterinary medicinal product *is homogeneously dispersed in the medicated feed and in* the intermediate product.
2. The Commission may, by means of implementing acts, establish criteria for the homogenous *dispersion* of the veterinary medicinal product into the medicated feed or into the intermediate product, taking into account the specific properties of the veterinary medicinal products and of the mixing technology. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

Article 7  
*Cross-contamination*

1. Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products shall apply measures in accordance with Article 4 **to avoid cross-contamination.**
2. The Commission *is* empowered to adopt delegated acts in accordance with Article 20 *in order to supplement this Regulation by establishing specific maximum levels of cross-contamination* for active substances *in non-target feed, unless such levels are already established in accordance with Directive 2002/32/EC. Those delegated acts may also set out methods of analysis for active substances in feed.*

*Regarding maximum levels of cross-contamination, those delegated acts shall be based on a scientific risk assessment carried out by EFSA.*

**█**

3. *The Commission shall, by ... [four years after the date of entry into force of this Regulation], adopt delegated acts in accordance with Article 20 in order to supplement this Regulation by establishing, as regards the antimicrobial active substances listed in Annex II, specific maximum levels of cross-contamination for active substances in non-target feed and methods of analysis for active substances in feed.*

*Regarding maximum levels of cross contamination, those delegated acts shall be based on a scientific risk assessment carried out by EFSA.*

4. *For active substances in the veterinary medicinal product which are the same as a substance in a feed additive, the applicable maximum level of cross-contamination in non-target feed shall be the maximum content of feed additive in complete feed established in the relevant Union act.*
5. *Until maximum levels of cross-contamination are established in accordance with paragraphs 2 and 3, Member States may apply national maximum levels of cross-contamination.*

Article 8  
Anticipated production

Medicated feed and intermediate products may be manufactured and *placed on the market, except as regards the supply to the animal keeper*, before the prescription referred to in Article 16 is issued.

The first paragraph of this Article shall not apply to:

- (a) on-farm mixers *and mobile mixers*;
- (b) manufacture of medicated feed or intermediate products *incorporating* veterinary medicinal products *intended to be used* in accordance with Article 112 or Article 113 of *Regulation (EU) 2018/...*<sup>+</sup>.

Article 9  
*Specific labelling requirements*

1. The labelling of medicated feed and intermediate products shall comply with Annex III to this Regulation.

*In addition, the specific requirements provided for in Regulation (EC) No 767/2009 for the labelling of feed materials and compound feed shall apply to medicated feed and intermediate products containing, respectively, feed materials or compound feed.*

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

2. Where containers are used instead of packages, they shall be accompanied by a document complying with paragraph 1.
3. Permitted tolerances for discrepancies between the labelled **content of an active substance** in a medicated feed or an intermediate product and the **content** analysed in official controls performed in accordance with Regulation (EU) 2017/625 shall be as set out in Annex IV to this Regulation.

## Article 10

### Packaging

1. Medicated feed and intermediate products shall be placed on the market only in sealed packages or containers. Packages or containers shall be sealed in such a way that, when the package or container is opened, the seal is damaged and cannot be reused. **Packages shall not be reused.**
2. **Paragraph 1 shall not apply to mobile mixers that supply medicated feed directly to the animal keeper.**

## *Article 11*

### *Advertising of medicated feed and intermediate products*

- 1. The advertising of medicated feed and intermediate products shall be prohibited. That prohibition shall not apply to advertising made exclusively to veterinarians.*
- 2. The advertising shall not include information in any form which could be misleading or lead to incorrect use of the medicated feed.*
- 3. Medicated feed shall not be distributed for promotional purposes except for small quantities of samples.*
- 4. Medicated feed containing antimicrobial veterinary medicinal products shall not be distributed for promotional purposes as samples or in any other presentation.*
- 5. The samples referred to in paragraph 3 shall be appropriately labelled indicating that they are samples and shall be given directly to veterinarians during sponsored events or by sales representatives during their visits.*

## Article 12

### Intra-Union trade *and import*

1. ***The feed business operator distributing medicated feed or intermediate products in a Member State which is different from the Member State where it was manufactured shall ensure that the veterinary medicinal products used for the manufacturing of that medicated feed or those intermediate products are allowed for use, in accordance with Regulation (EU) 2018/...<sup>+</sup>, in the Member State of use.***
  
2. ***The feed business operator importing medicated feed or intermediate products into the Union shall ensure that the veterinary medicinal products used for the manufacturing of that medicated feed or those intermediate products are allowed for use, in accordance with Regulation (EU) 2018/...<sup>+</sup>, in the Member State of use.***

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

Chapter III  
Approval of establishments

Article 13  
Approval obligations

1. Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products shall ensure that establishments under their control are approved by the competent authority.
2. *Paragraph 1 shall not apply to the following feed business operators:*
  - (a) *those who only buy, store or transport medicated feed for the exclusive use on their farm;*
  - (b) *those who act solely as traders, without holding the medicated feed or intermediate products in their premises;*
  - (c) *those who only transport or store medicated feed or intermediate products exclusively in sealed packages or containers.*
3. *The competent authority shall approve establishments only where an on-site visit, prior to start-up of the relevant activity, has demonstrated that the system put in place for the manufacture, storage, transport or placing on the market of medicated feed or intermediate products meets the specific requirements of Chapter II.*

4. *In the event that mobile mixers place medicated feed on the market in a Member State different from the one where they are approved, such mobile mixers shall notify that activity to the competent authority in the Member State where the medicated feed is placed on the market.*
5. *In respect of retailers of medicated feed for pets and keepers of fur animals feeding animals with medicated feed, Member States shall have in place national procedures to ensure that relevant information regarding their activities is available to the competent authorities, while avoiding duplication and unnecessary administrative burden.*

#### Article 14

##### ■ Lists of approved establishments

*The establishments approved in accordance with Article 13(1) of this Regulation shall be recorded in a national list, as referred to in Article 19(2) of Regulation (EC) No 183/2005, under an individual identifying number attributed in the form set out in Chapter II of Annex V to that Regulation.*

■

## Article 15

### ***Transitional measures concerning the implementation of the requirements for approval and registration***

1. Establishments falling within the scope of this Regulation which have already been approved in accordance with Directive 90/167/EEC ***or otherwise authorised by the competent authority for activities falling within the scope of this Regulation*** may continue their activities subject to the submission, by ... [42 months after the date of entry into force of this Regulation], of a declaration to the relevant competent authority in the area where their facilities are located, in a form decided upon by that competent authority, that they meet the requirements for approval referred to in Article ***13(3) of this Regulation***.
2. ***Where the declaration referred to in paragraph 1 of this Article is not submitted within the period specified, the competent authority shall suspend the existing approval in accordance with the procedure referred to in Article 14 of Regulation (EC) No 183/2005.***

Chapter IV  
Prescription and use

Article 16  
Prescription

1. The supply of medicated feed to animal *keepers* shall be subject to:
  - (a) the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription *for medicated feed*; and
  - (b) the conditions laid down in paragraphs 2 to 10.
2. *A veterinary prescription for medicated feed shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian and only for a diagnosed disease.*
3. *By way of derogation from paragraph 2, a veterinary prescription for medicated feed containing immunological veterinary medicinal products may be issued also in the absence of a diagnosed disease.*
4. *By way of derogation from paragraph 2, if it is not possible to confirm the presence of a diagnosed disease, a veterinary prescription for medicated feed containing antiparasitics without antimicrobial effects may be issued based on the knowledge of the parasite infestation status in the animal or group of animals.*

5. *By way of derogation from point (h) of Article 3(2) and paragraph 2 of this Article, a Member State may allow a veterinary prescription for medicated feed to be issued by a professional person qualified to do so in accordance with applicable national law on ... [the date of entry into force of this Regulation].*

*Such prescriptions shall exclude prescription of medicated feed containing antimicrobial veterinary medicinal products or any other veterinary medicinal products where a diagnosis by a veterinarian is necessary and shall be valid only in that Member State.*

*The professional person referred to in the first subparagraph shall, when issuing such a prescription, make any necessary verifications in accordance with national law.*

*Paragraphs 6, 7, 8 and 10 of this Article shall apply, mutatis mutandis, to such prescriptions.*

6. The *veterinary prescription for medicated feed* shall contain the information set out in Annex V.

The original *veterinary prescription for medicated feed* shall be kept by the manufacturer or, where appropriate, the *feed business operator supplying the medicated feed to the animal keeper*. The *veterinarian, or the professional person referred to in paragraph 5*, issuing the prescription and the *keeper of food-producing or fur animal* shall keep a copy of the *veterinary prescription for medicated feed*.

The original and copies shall be kept for *five* years from the date of issuance.

7. With the exception of medicated feed for non-food-producing animals, ***other than fur animals***, medicated feed shall not be used for more than one treatment under the same ***veterinary*** prescription ***for medicated feed***.

***The duration of a treatment shall comply with the summary of product characteristics of the veterinary medicinal product incorporated in the feed and, where not specified, shall not exceed one month, or two weeks in case of a medicated feed containing antibiotic veterinary medicinal products.***

8. The ***veterinary*** prescription ***for medicated feed*** shall be valid ***from the date of its issuance*** for a maximum period of six months for non-food-producing animals ***other than fur animals*** and three weeks for food-producing animals ***and fur animals***. ***In the case of medicated feed containing antimicrobial veterinary medicinal products, the prescription shall be valid from the date of its issuance for a maximum period of five days.***

9. The ***veterinarian*** issuing the ***veterinary*** prescription ***for medicated feed*** shall verify that this medication is justified for the target animals on veterinary grounds. Furthermore that veterinarian shall ensure that the administration of the veterinary medicinal product concerned is not incompatible with another treatment or use and that there is no contra-indication or interaction where several medicinal products are used. ***In particular, the veterinarian shall not prescribe medicated feed with more than one veterinary medicinal product containing antimicrobials.***

10. The *veterinary prescription for medicated feed* shall: ■
- (a) *comply with the summary of the product characteristics of the veterinary medicinal product, except for veterinary medicinal products intended to be used in accordance with Article 112, Article 113 or Article 114 of Regulation (EU) 2018/...<sup>+</sup>;*
  - (b) *indicate the daily dose of the veterinary medicinal product which is to be incorporated in a quantity of medicated feed that ensures the uptake of the dosage by the target animal considering that the feed uptake of diseased animals might differ from a normal daily ration;*
  - (c) *ensure that the medicated feed containing the dosage of the veterinary medicinal product corresponds to at least 50 % of the daily feed ration on a dry matter basis and that, for ruminants, the daily dose of the veterinary medicinal product is contained in at least 50 % of the complementary feed except for mineral feed;*
  - (d) *indicate the inclusion rate of the active substances, calculated on the basis of the relevant parameters.*

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

11. *Veterinary prescriptions for medicated feed issued in accordance with paragraphs 2, 3 and 4 shall be recognised throughout the Union.*
12. *The Commission may, by means of implementing acts, set a model format for the information set out in Annex V. That model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).*

#### Article 17

##### Use of medicated feed

1. *The prescribed medicated feed shall be used only for animals for which the veterinary prescription for medicated feed has been issued in accordance with Article 16.*
2. *Animal keepers shall use medicated feed only in accordance with the veterinary prescription for medicated feed, take measures to avoid cross-contamination and shall ensure that only the identified animals in the veterinary prescription for medicated feed are administered with the medicated feed. Animal keepers shall ensure that expired medicated feed is not used.*
3. *Medicated feed containing antimicrobial veterinary medicinal products shall be used in accordance with Article 107 of Regulation (EU) 2018/...<sup>+</sup>, except as regards paragraph 3 thereof, and shall not be used **■** for prophylaxis.*
4. *Medicated feed containing immunological veterinary medicinal products shall be used in accordance with Article 110 of Regulation (EU) 2018/...<sup>+</sup> and shall be used on the basis of a prescription in accordance with Article 16(3) of this Regulation.*

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<sup>+</sup> *OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).*

5. ***Medicated feed containing antiparasitics shall be used on the basis of a prescription in accordance with Article 16(4) of this Regulation.***
6. When administering medicated feed, the ***keeper*** of food-producing animals shall ensure compliance with the withdrawal period provided for in the veterinary prescription ***for medicated feed.***
7. ***The keeper of*** food-producing animals ***feeding them*** with medicated feed shall keep records in accordance with Article ***108 of Regulation (EU) 2018/...***<sup>‡</sup>. Those records shall be kept for at least five years after the date of administration of medicated feed, including when the ***food-producing*** animal is slaughtered during the five-year period.

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

## Article 18

### Collection or discard systems of unused or expired products

Member States shall ensure that appropriate collection *or discard* systems are in place for medicated feed and intermediate products that are expired or in case the animal *keeper* has received a bigger quantity of medicated feed than he actually used for the treatment referred to in the veterinary prescription *for medicated feed*.

*Member States shall take measures to ensure that relevant stakeholders are consulted as regards such systems.*

*Member States shall take measures to ensure that the location of collection or discard points as well as other relevant information is made available to farmers, animal keepers, veterinarians and other relevant persons.*

## Chapter V

### Procedural and final provisions

## Article 19

### Amendment of Annexes

The Commission *is* empowered to adopt delegated acts in accordance with Article 20 amending Annexes I to V, in order to take into account technical progress and scientific developments.

## Article 20

### Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in Articles 7 and **19** shall be conferred on the Commission for *a period of five years* from ... [the date of entry into force of this Regulation]. *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of powers referred to in Articles 7 and **19** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. *Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.*

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 7 and **19** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

### Article 21

#### Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 (the ‘Committee’). That Committee is a Committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where the opinion of the Committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the Committee so decides or a simple majority of Committee members so request.

## Article 22

### Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.
2. Member States shall, by ... [**36 months** after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

## Article 23

### *Amendment to Regulation (EC) No 183/2005*

*Article 5 of Regulation (EC) No 183/2005 is amended as follows:*

*(1) in paragraph 1, point (c) is replaced by the following:*

*'(c) mixing of feed, for the exclusive requirements of their own holdings, without using veterinary medicinal products or intermediate products as defined in Regulation (EU) 2018/...<sup>\*+</sup> or additives or premixtures of additives, with the exception of silage additives,*

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*\* Regulation (EU) 2018/.... of the European Parliament and of the Council of ... on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L ..., p. ...).';*

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*+ OJ: please insert the number, date and OJ reference of this Regulation.*

(2) *paragraph 2 is replaced by the following:*

'2. *For operations other than those referred to in paragraph 1, including mixing of feed for the exclusive requirements of their own holdings when using veterinary medicinal products or intermediate products as defined in Regulation (EU) 2018/...<sup>+</sup> or additives or premixtures of additives, with the exception of silage additives, feed business operators shall comply with Annex II, where relevant for the operations carried out.'*

#### *Article 24*

##### *Transitional measures*

*Without prejudice to the date of application referred to in Article 26, the Commission is empowered to adopt the delegated acts provided for in Article 7(3) from ... [the date of entry into force of this Regulation].*

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<sup>+</sup> *OJ: please insert the number of this Regulation.*

## Article 25

### Repeal

Directive 90/167/EEC is repealed.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VI to this Regulation.

## Article 26<sup>+</sup>

### Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [**36 months** after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

*For the European Parliament*

*For the Council*

*The President*

*The President*

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<sup>+</sup> OJ: please ensure that this Regulation enters into force at the same time as Regulations contained in documents PE-CONS 45/18 (2014/0257(COD)) and PE-CONS 44/18 (2014/0256(COD)).

## ANNEX I

### *Specific requirements for feed business operators in accordance with Article 4*

#### SECTION 1

##### FACILITIES AND EQUIPMENT

1. Feed business operators shall **ensure that** facilities and equipment and their immediate surroundings are kept clean. Cleaning **plans** shall be introduced **and be drawn up in writing, in order to** ensure that any contamination, including cross-contamination is minimised.
2. *Feed business operators shall ensure that access to all facilities is restricted to authorised personnel.*

#### SECTION 2

##### PERSONNEL

1. **An adequately trained** person responsible for the manufacture, **placing on the market and supply to the animal keeper** of medicated feed and intermediate products and an **adequately trained** person responsible for quality control shall be designated.
2. *With the exception of mobile mixers and on-farm mixers, the functions of the person responsible for manufacture and person responsible for quality control shall be independent of each other and therefore shall not be carried out by the same person.*

SECTION 3  
MANUFACTURE

1. Feed business operators shall take account of requirements under relevant systems of quality assurance and good manufacturing practices, developed in accordance with Article 20 of Regulation (EC) No 1831/2003.

■

2. Medicated feed and intermediate products shall be stored separately from any other feed in order to avoid any cross-contamination.
3. *Veterinary medicinal products shall be stored in a separate secured room and in such a way that their characteristics are not altered.*
4. *The material used for cleaning the production line after the manufacturing of medicated feed or intermediate products, shall be identified, stored and managed in such a way as not to affect the safety and quality of the feed.*

SECTION 4  
QUALITY CONTROL

1. A quality control plan shall be drawn up in writing and implemented. It shall include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications ***for the medicated feed and intermediate products*** and the measures to be taken in the event of non-compliance.

***The quality control plan should define rules regarding sequencing or incompatibilities of manufacturing operations and, where applicable, define the need for dedicated production lines.***

2. Specific regular own checks ***as well as stability tests*** shall ensure compliance with the homogeneity criteria as laid down in accordance with Article 6(2), the ***maximum levels of cross-contamination for active substance in non-target feed*** as laid down in accordance with Article 7(2) and the minimum storage life of the medicated feed ***and the intermediate products***.

SECTION 5  
STORAGE AND TRANSPORT

1. Medicated feed and intermediate products shall be stored in suitable separate and secured *facilities* or sealed in hermetic containers which are specially designed for the storage of such products. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions.
2. ***Veterinary medicinal products shall be stored in separate, safe and secure areas. Those areas shall be of sufficient capacity and properly identified to allow orderly storage of the various veterinary medicinal products.***

Medicated feed and intermediate products shall be stored and transported in such a way as to be easily identifiable. Medicated feed and intermediate products shall be transported in suitable means of transport.

3. ***Specific facilities shall be identified for the storage of expired, withdrawn or returned medicated feed and intermediate products.***
4. ***Containers in vehicles used for the transport of medicated feed or intermediate products shall be cleaned after each use to avoid any risk of cross-contamination.***

SECTION 6  
RECORD-KEEPING

1. Feed business operators manufacturing, storing, transporting or placing on the market medicated feed and intermediate products shall keep in a *record* relevant data, comprising details of purchase, manufacturing, storage, transport and placing on the market for effective tracing from receipt to delivery, including export to the final destination.
2. The *record* referred to in paragraph 1 of this Section shall contain:
  - (a) the HACCP documentation referred to in point (g) of Article 6(2) *and in Article 7(1)* of Regulation (EC) No 1831/2003;
  - (b) the quality control plan *provided for in Section 4 of this Annex* and the results of the relevant controls;
  - (c) specifications and quantities of veterinary medicinal products *with batch number*, feed materials, compound feed, feed additives, intermediate products and medicated feed which have been purchased;
  - (d) specifications and quantities of the batches of medicated feed and intermediate products which have been manufactured, including the veterinary medicinal products *with batch number*, feed materials, compound feed, feed additives and intermediate products which have been used;

- (e) specifications and quantities of the batches of medicated feed and intermediate products which have been stored or transported;
- (f) specifications and quantities of medicated feed and intermediate products which have been placed on the market or exported to third countries, *including the unique number of the veterinary prescription for medicated feed*;
- (g) information on the manufacturers or suppliers of the medicated feed and intermediate products or of the products used for the manufacture of medicated feed and intermediate products, including at least their name, address and, where applicable, their approval identifying number;
- (h) information on the recipients of the medicated feed and intermediate products, including at least their name, address and, where applicable, their approval identifying number; and
- (i) information on the *veterinarian, or the professional person referred to in Article 16(5)*, who has issued the *veterinary prescription for medicated feed*, including at least *that veterinarian's or that professional person's* name and address.

■ The documents listed in this paragraph shall be kept for at least **five** years in the **record** after their date of issuance.

SECTION 7  
COMPLAINTS AND PRODUCT RECALL

1. Feed business operators placing medicated feed and intermediate products on the market shall implement a system for registering and processing complaints.
2. **Feed business operators** shall put in place a system for the prompt withdrawal from the market of medicated feed or intermediate products and, if necessary, for the recall of medicated feed or intermediate products from the distribution network in case they fail to comply with the requirements of this Regulation.

**Feed business operators** shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation **the feed business operators** shall **carry out** a quality-control reassessment **to ensure that the Union feed safety requirements are complied with.**

## **SECTION 8**

### **ADDITIONAL REQUIREMENTS FOR MOBILE MIXERS**

1. Mobile mixers shall have a copy of the following documents available in the vehicle, in the official language of the Member State where the manufacture of medicated feed takes place:
  - (a) *the approval of the designated mobile mixer for the manufacture of medicated feed from the competent authority from the Member State where the mobile mixer is approved;*
  - (b) *the HACCP documentation referred to in point (g) of Article 6(2) and in Article 7(1) of Regulation (EC) No 183/2005;*
  - (c) *the quality control plan provided for in Section 4 of this Annex;*
  - (d) *the cleaning plan referred to in Section 1 of this Annex;*
  - (e) *the list of persons responsible for the manufacture of medicated feed referred to in Section 2 of this Annex.*
2. *Mobile mixers shall take all the appropriate precautionary measures to prevent the spread of diseases. Vehicles used for the manufacture of medicated feed shall be cleaned after each use for the manufacture of medicated feed to avoid any risk of cross-contamination.*
3. *Where vehicle registration plate numbers are available, mobile mixers shall use only those vehicles whose vehicle registration plate numbers have been notified to the competent authority.*

**ANNEX II**

***List of antimicrobial active substances as referred to in Article 7(3)***

<b>Active substance</b>
<b>1. Amoxicillin</b>
<b>2. Amprolium</b>
<b>3. Apramycin</b>
<b>4. Chlortetracycline</b>
<b>5. Colistin</b>
<b>6. Doxycycline</b>
<b>7. Florfenicol</b>
<b>8. Flumequine</b>
<b>9. Lincomycin</b>
<b>10. Neomycin</b>

<b>11. Spectinomycin</b>
<b>12. Sulfonamides</b>
<b>13. Tetracycline</b>
<b>14. Oxytetracycline</b>
<b>15. Oxolinic Acid</b>
<b>16. Paromomycin</b>
<b>17. Penicillin V</b>
<b>18. Tiamulin</b>
<b>19. Tiamfenicol</b>
<b>20. Tilimicosin</b>
<b>21. Trimethoprim</b>
<b>22. Tylosin</b>
<b>23. Valnemulin</b>
<b>24. Tylvalosin</b>

## ANNEX III

### *Specific labelling requirements referred to in Article 9(1)*

The label of medicated feed and intermediate products shall include the following particulars, *in a simple, clear and easily understandable manner for the end users*:

- (1) the expression 'Medicated feed' or 'Intermediate product for *the manufacturing of medicated feed*' as appropriate ;  
■
- (2) the approval number of the ■ *feed business operator* responsible for the labelling. *In cases where the manufacturer is not the feed business operator responsible for the labelling, the following shall be provided:*
  - (a) *the name or business name and address of the manufacturer; or*
  - (b) *the approval number of the manufacturer;*
- 
- (3) the *active substances* with name, ■ added amount (*mg/kg*), *and the veterinary medicinal products with its marketing authorisation* ■ number *and the marketing authorisation holder*, preceded by the heading 'medication';
- (4) ■ any contra-indications *of the veterinary medicinal products* and adverse events in so far as these particulars are necessary for the use;

- (5) in the case of a medicated feed or of intermediate product intended for food-producing animals, the withdrawal period or the indication ‘no *withdrawal period*’;
- (6) *in the case of medicated feed for non-food-producing animals, except fur animals*, a warning that the *medicated feed* is only for the treatment of animals and a warning that *it* must be kept out of the sight and reach of children;

- 
- (7) ■ a free telephone number or other appropriate means of communication in order to allow the *animal keeper* to obtain, in addition to the mandatory particulars, ■ *the package leaflet of each veterinary medicinal product*;

- 
- (8) the instructions for use in line with the veterinary prescription *for medicated feed* or the summary of the product characteristics ■ ;
- (9) the minimum storage life, *which shall take into account the expiry dates of the veterinary medicinal products and shall be expressed as ‘use before...’, followed by the date*, and special storage precautions, if appropriate;
- (10) *information that inappropriate disposal of medicated feed poses serious threats to the environment and may, where relevant, contribute to antimicrobial resistance.*

*Points 1 to 10 shall not apply to mobile mixers exclusively manufacturing the medicated feed without supplying any components.*

## ANNEX IV

### Permitted tolerances for the compositional labelling of medicated feed or intermediate products as referred to in Article 9(3)

The tolerances laid down in this Annex shall *only* include technical deviations.

Where the composition of a medicated feed or an intermediate product is found to deviate from the amount of an antimicrobial active substance indicated on the label, a tolerance of 10 % shall apply.

For the other active substances, the following tolerances shall apply:

Active substance per kg of medicated feed <i>or</i> <i>intermediate products</i>	Tolerance
> 500 mg	± 10 %
≤ 500 mg	± 20 %

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## ANNEX V

### *Information to be included in the veterinary prescription for medicated feed as referred to in Article 16(6)*

#### **VETERINARY PRESCRIPTION FOR MEDICATED FEED**

1. Full name and contact details of the veterinarian including, if available, the professional **■** number **■** .
2. Issue date, unique number of prescription, expiry date of prescription (if the validity is shorter than that referred to in Article 16(8)) and signature or an equivalent electronic form of identification of the veterinarian.
3. Full name and contact details of the animal keeper, and identification number of the establishment, if existing.
4. Identification (including category, species and age) and number of animals or, where appropriate, the weight of the animals.
5. Diagnosed disease to be treated. In the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects, disease to be prevented.
6. Designation (***name and marketing authorisation number***) of the veterinary medicinal product or products, including the name of the active substance or substances.
7. If the veterinary medicinal product is prescribed under Article 107(4), Article 112, Article 113 or Article 114, of Regulation (EU) 2018/...<sup>+</sup>, a statement to that effect.

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<sup>+</sup> ***OJ: please insert the number of the Regulation contained in document PE-CONS 45/18 (2014/0257(COD)).***

8. Inclusion rate of the veterinary medicinal product or products *and active substance or substances* (quantity per weight unit of medicated feed).
9. Quantity of medicated feed.
10. Instructions for use for the animal *keeper*, including the duration of the treatment.
11. Percentage of medicated feed in the daily ration or quantity of medicated feed per animal and day.
12. For food-producing animals, withdrawal period, even if such period is zero.
13. Any **■** warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials.
14. For food-producing animals *and fur animals*, the mention 'This prescription shall not be re-used'.
15. The following mentions to be completed by the supplier of the medicated feed or the on-farm mixer, as appropriate:
  - name or business name and address,
  - date of delivery or of on-farm mixing,
  - *batch number of medicated feed delivered under the veterinary prescription for medicated feed, except for on-farm mixers.*
16. Signature of supplier *to the animal keeper* or of on-farm mixer.

## ANNEX VI

### Correlation table referred to in Article 25

Directive 90/167/EEC	This Regulation
Article 1	Article 2
Article 2	Article 3
Article 3(1)	Article 5(1)
Article 3(2)	-
Article 4(1)	Articles 4, 5(2), 6, 7(1), 13, 16 and Annex I
Article 4(2)	-
Article 5(1)	Article 10
Article 5(2)	Articles 4, 7 and Annex I
-	Article 8
Article 6	Article 9 and Annex III
Article 7	-
Article 8(1) and (2)	Article 16
Article 8(3)	Article 17(6)
Article 9(1)	Articles 13,17(1) and (2)
Article 9(2)	-

Article 9(3)	-
-	Article 11
Article 10	Article 12(1)
-	Article 14
-	Article 15
-	Article 17(3), (4) and (5)
-	Article 17(7)
-	Article 18
Article 11	-
Article 12	Article 19
-	Article 20
-	Article 21
-	Article 22
-	Article 25
-	Article 26
Article 13	-
Article 14	Article 12(2)
Article 15	-
Article 16	-
Annex A	Annex V
Annex B	-

-	Annex II
-	Annex IV

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